UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,346	01/20/2006	Jane Hirsh	PDX-007.01	1923

25181 7590 03/11/2011

FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
03/11/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent@foleyhoag.com

Office Action Summary	Application No.	Applicant(s)	
	10/565,346	HIRSH ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,13,15 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11,13,15 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/14/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Amendments and Remarks filed on 12/28/10 and a new IDS filed on 07/14/10. Claim 1 has been amended, new claim 19 has been added and claims 12, 14 and 16-18 have been cancelled. Accordingly, claims **1, 3-11, 13, 15 and 19** are pending and under examination on the merits.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim **13** is indefinite for depending on a cancelled claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-11, 13, 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al (US 20060140984) in view of Davis (5,143,717) and in further view of Sachetto (WO 9603115A1).

Tamarkin et al '984 disclose an **alcohol-free cosmetic or pharmaceutical foam** carrier comprising water, a hydrophobic solvent, a foam adjuvant agent, a surface-active agent and a water gelling agent (see abstract). The said alcohol-free foamable carriers, when placed in an aerosol container and combined with a liquefied gas propellant, create an oil in water emulsion, which upon release from the aerosol container, provides a therapeutically beneficial foam product (see [0025]). The foam carrier includes active agents, both water soluble and oil soluble (see [0063]). The foam is easily spreadable, allowing treatment of large areas as the arms, back, legs and breast (see [0064]). One suitable foaming adjuvant/surfactant is cetyl alcohol (see [0081]). Examples of suitable propellants include volatile hydrocarbons such as butane

and fluorocarbon gases, which are present from about **5 to 25%** based on the carrier (see [0115]). Examples of suitable active agents include antibiotics, antifungals, anesthetics, anti-inflammatory agents, corticosteroids, etc (see [0226]). Anti-inflammatory agents include clobetasone, betamethasone, diclofenac, ketorolac, ibuprofen (see [0245] and [0252]-[0257]). Anti-fungals include fluconazole, ketoconazole, clotrimazole, etc (see [0234] to [0237]). Antibiotics include penicillins, macrolides, beta-lactams, etc ([0229]). Anesthetics include lidocaine, bupivacaine, dibucaine, etc (see [0264]). Example 8 discloses a foam formulation comprising antibacterials in an amount of about 2%. Example 9 discloses a foam formulation comprising 1-2% antifungals, about 5.6% oil and 85.2% water. Example 10 discloses foam formulations comprising 0.05 to 1% of corticosteroid anti-inflammatory agents. Example 18 discloses a foam formulation comprising 4% lidocaine. Example 1 discloses a method of preparing the foam formulations.

Tamarkin et al '984 lacks disclosure on the oil phase being solid or semi-solid at room temperature. This deficiency has been remedied by Davis.

Tamarkin et al also lacks specific disclosure on hydrofluroalkanes as propellants. However this deficiency has been cured by Sachetto.

Davis teaches burn foam and delivery system. The said foam is an antibiotic formulation useful in the treatment of burns and abrasions and adapted for topical application as a clinically water soluble foam (see abstract). The process steps in

preparation of the said foam formulation include **heating and melting** the white petrolatum and other ingredients until all dints are melted and thoroughly to form the **oil phase** of the emulsion (see col. 4, lines 26-40). In a table on columns 5-6, multiple formulations have been exemplified with the concentration of each component. Examples VI-XV appear to contain an oil phase that is less than 3% (white petrolatum at 2.45%). The formulations also comprise a mixture of propane and isobutene as the propellant portion.

Sachetto teaches aqueous foamable compositions comprising active agents surfactants and foaming agents. The foaming agent is preferably a so-called liquefied gas, including propane, butane, isobutene or environmentally friendly propellants such as HFA 134a and HFA 227 (see page 4 and Table 1). Such foamable formulations have been exemplified in examples 1-21. Tables such as Table IV, discloses ingredients used in examples 10-14, which include a foaming agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Tamarkin et al '984, Davis and Sachetto on forming foam compositions with a reasonable expectation of successfully preparing stable foam formulations for treating various disorders topically. Tamarkin et al teach an alcohol-free foam composition where the oil phase is liquid at room temperature and Davis teaches a foam formulation where the oil phase is solid at room temperature. Tamarkin discloses that the foam formulations comprise a propellant and

Sachetto discloses that propellants such as HFAs are suitable and environmentally friendly propellants and are used in foam formulations. One of ordinary skill in the art could have selected the solid phase of Davis over the liquid phase of Tamarkin et al with predictable results. In other words, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 1, 3-11, 13, 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamarkin et al (US 20060233721) in view of Quigley, Jr. et al (6,075,056) and in further view of Sachetto (WO 9603115A1).

Tamarkin et al '721 teach foamable composition for administration to the skin, body surface, body cavity or mucosal surface, e.g. the mucosa of the nose, mouth, eye, ear, respiratory system, etc. The foamable oil in water emulsion composition includes: an oil globule system, selected from the group consisting of oil bodies; and sub-micron oil globules, about 0.1% to about 5% by weight of an agent, selected from the group consisting of a surface-active agent, having an HLB value between 9 and 16 and a polymeric agent and a liquefied or compressed gas propellant at a concentration of about **3% to about 25%** by weight of the total composition, water and optional ingredients are added to complete the total mass of 100% (see abstract and [0012]).

The said foamable composition further includes at least one therapeutic agent such as an anti-inflammatory agent, antifungal or antibacterial, anesthetics etc (see [0026]). A polar solvent such as polyols ([0064]). The foamable compositions may be substantially alcohol-free, i.e. **free of short chain alcohols**, having up to 5 carbon atoms in their carbon chain skeleton (see [0066]). The formulations may be in an oil-in-water emulsion ([0080]). Suitable propellants include volatile hydrocarbons and fluorocarbon gases ([0098]). Claim 1 is drawn to a foamable oil in water emulsion composition comprising an oil globule, a non-ionic surface active agent, water and a liquefied propellant. One suitable foam adjuvant/surfactant is cetyl alcohol (see [0091]).

Tamarkin et al '721 does not disclose an oil phase wherein the emulsion is a solid or semi-solid at room temperature. This deficiency has been remedied by Quigley et al. Tamarkin et al also lacks specific disclosure on hydrofluroalkanes as propellants. However this deficiency has been cured by Sachetto.

Quigley, Jr. et al teach stable topical formulations comprising an antifungal agent and an anti-inflammatory steroid useful for treating fungal diseases and their related inflammation (see abstract). The topical formulations may be in the form of foam, cream, lotion, solution, etc (see col. 7, lines 31-34). To prepare the oil phase of the said topical formulations, it is said that the drugs are dissolved in the oil phase consisting of melted oil-soluble components of the formulation prior to addition of this phase to the aqueous phase (see col. 8, line 65 to col. 9, line 3). Other examples disclose similar

process steps. Quigley et al also discloses that "white petrolatum is an emollient cream base and can be replaced by mineral oil" (see col. 8, lines 50-51). The cream formulations in Tables A and B show formulations comprising less than 10% oil phase (from 2 to 10% glycerin in Table A and from 1-20% white petrolatum in Table B).

Sachetto teaches aqueous foamable compositions comprising active agents surfactants and foaming agents. The foaming agent is preferably a so-called liquefied gas, including propane, butane, isobutene or environmentally friendly propellants such as HFA 134a and HFA 227 (see page 4 and Table 1). Such foamable formulations have been exemplified in examples 1-21. Tables such as Table IV, discloses ingredients used in examples 10-14, which include a foaming agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Tamarkin et al '721, Quigley, Jr. et al and Sachetto on stable topical formulations comprising active agents such as antifungal agents and anti-inflammatory steroids useful for treating various diseases with a reasonable expectation of successfully preparing stable and effective topical foam preparations. Tamarkin et al teach foam formulations wherein the oil phase is a liquid at room temperature and the formulations are substantially free of lower alcohols. Quigley teaches topical formulations that can be in the form of foam and wherein the oil phase of the oil-in-water emulsion is soli or semi-solid at room temperature and is mixed with the aqueous phase after being melted. Tamarkin discloses that the foam

formulations comprise a propellant and Sachetto discloses that propellants such as HFAs are suitable and environmentally friendly propellants and are used in foam formulations. One of ordinary skill in the art would have been able to select the solid oil phase of Quigley and the substantially free of alcohols foam formulation of Tamarkin et al with expected results. That is, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Additionally, the claims would have been obvious because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Response to Remarks

Applicant's arguments filed 12/28/10 have been fully considered but they are not persuasive.

Applicant's main argument appears to be with regard to Sachetto reference and that Sachetto discloses a co-solvent or co-propellant for his foam formulations. Applicant states that "An aerosol foam formulation containing a hydrofluoroalkane (HFA) propellant without a co-propellant was not "obvious to try" at the time of invention based on the cited references. As the Examiner mentions, Sachetto is the lone reference to disclose HFA propellants. However, the formulations described in Sachetto require the

presence of a propellant or a co-propellant, in addition to the "foaming agent in the form of a water-immiscible liquefied gas," in order successfully to form a foam. Sachetto, page 10-11. Sachetto describes in detail the three kinds of aerosol containers that must be used with the described formulations: "the conventional 'monobloc' system; the 'bag-in-can' system and the 'can with piston' system." Sachetto, page 10, lines 30-31. Sachetto then discloses that the "bag-in-can" system and the "can with piston" system require a propellant separate from the formulation; that is, a propellant not in admixture with the formulation. The "monobloc" system similarly requires a co-propellant to be added to the can with the foamable composition. Nitrogen is the sole example provided by Sachetto of an appropriate additional propellant or co-propellant. In any kind of container, the formulations of Sachetto require the presence of an additional propellant or a co-propellant to form successfully a foam. Indeed, each example described in Sachetto is in the bag-in-can form and utilizes an additional propellant. Sachetto, page 12. Consequently, based on the cited references, one of ordinary skill would not have considered the use of a HFA propellant without a co-propellant "obvious to try."".

The above statements are not persuasive to obviate the rejection. Firstly it is noted that Applicant makes no reference to the Tamarkin et al references. Tamarkin et al teach alcohol-free foam formulations in the form of an oil-in-water emulsion comprising every component of the instant claimed foam formulations except for the HFA propellant. Tamarkin et al do disclose that the formulations comprise a propellant, however they do not recite HFA propellants as the propellants of their choice. The foam formulations of Tamarkin et al contain an oil phase, a water phase and a propellant

without the use of co-solvents or co-propellants. Sachetto reference was relied upon for its disclosure of suitable propellants for foam formulations including HFA propellants. As such it has been clearly disclosed that by simple substitution of Sachetto's HFA propellants in Tamarkin et al's foam formulations one of ordinary skill in the art would have arrived at the claimed foam formulations.

Applicant does not articulate why one of ordinary skill in the art would not have had success by substituting HFA propellants for the propellants of Tamarkin et al. Applicant merely states that "the combination of cited references fails to teach or render "obvious to try" the additional claim limitations in an enabling disclosure". Applicant further discloses that "Importantly, the Applicant maintains that the challenges associated with preparing HFA-containing formulations are well- documented within this record and in the art, generally. None of the cited references provides guidance whatsoever with respect to overcoming these challenges. Notwithstanding the fact that various topical formulations are known to contain many different components, and the fact that HFA propellants were known at the time of invention, in the parlance of Impax the Applicant maintains that the cited references do not provide sufficient direction or guidance to allow a skilled artisan to arrive at the claimed invention".

Again, this is not persuasive. Tamarkin et al disclose the same formulations as claimed except for the specific HFA propellants. Tamarkin et al disclose that suitable propellants include butane, propane, isobutane. Sachetto discloses that in foam formulations any of the disclosed propellants may be used. The suitable propellants include, isobutene, propane, butane and HFAs. It is also disclosed that HFAs are the

environmentally friendly propellants. Applicant does not state why one of ordinary skill in the art would not have been motivated to select HFAs as the propellants and end up with the claimed foam formulations. Sachetto, by disclosing butane and isobutene in the same Markush as HFAs, teach that one can be substituted for the other. In other words Sachetto teach that the said propellants are functionally equivalent. Also Sachetto teach that HFAs are the more recent and environmentally friendly propellants which by itself is motivation for one of ordinary skill in the art to select them.

Applicant then argues that "Assuming arguendo that all of the limitations of a rejected claim are taught or suggested in an enabled fashion by the combination of references relied upon by the Examiner, or that any missing limitations are among the variations that would have been "obvious to try" to one of ordinary skill, the Applicant respectfully asserts that one of ordinary skill in the art would have had no reasonable expectation of success in arriving at the claimed invention. A reasonable artisan would not have expected success in using hydrofluorocarbon propellants for immediate foaming emulsion compositions without the use of a separate propellant or without the use of lower volatile alcohols or both. Importantly, Sachetto is the lone reference to disclose HFA propellants. However, as mentioned above, the formulations described in Sachetto require the presence of a propellant or a co-propellant, in addition to the "foaming agent in the form of a water-immiscible liquefied gas," in order successfully to form a foam. Sachetto, page 10-11".

The above arguments are not persuasive and do not overcome the rejections because Sachetto teach that the foaming agent is a liquefied gas including butane,

propane or HFAs (see page 4). In page 6, Sachetto explicitly discloses a composition comprising the listed components. The only solvent is water and the only foaming agent is a liquefied gas. In all of the disclosed examples, only one propellant and water are disclosed. In page 10, Sachetto discloses a process of making the forma formulation which include transferring the concentrate into a pressurized mixing tank, where it is blended with the foaming agent". The monobloc systems are specifically taught for use as rectal applications and it is disclosed that such systems may require a separate propellant.

In summary, Applicant's arguments are not persuasive because 1) Tamarkin et al, the primary reference discloses each and every limitation of the claimed foam formulations except for propellant being an HFA, which is taught by Sachetto. 2) Even if Sachetto was to be relied upon for its teachings of the foam formulations, it has been clearly shown that it discloses foam formulations comprising no co-solvents and no co-propellants.

Claims 1, 3-11, 13, 15 and 19 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616